

ANALYSIS OF MARKET RESEARCH DATA ON THE ICY HOT® PATCH

Manufacturers of over-the-counter products routinely conduct market research to identify consumer interest in and reaction to new products or modifications of existing products. Although not conducted under scientifically rigorous conditions, market research studies can provide valuable and supportive data regarding the safety profile of products. In addition, such studies can provide information on whether products are convenient to use, whether they meet consumer needs, and on how consumers use them. Six market research studies sponsored by Chattem, Inc. ("Chattem") provide relevant data on the Icy Hot® Patch and Icy Hot® Back Patch; these are summarized in the attached table and discussed below. Data from these studies help to support the following conclusions.

ICY HOT® PATCHES ARE SAFE

The six market research studies conducted by Chattem provide supportive evidence that use of Icy Hot® Patches is not associated with significant safety issues. Although none of the studies was conducted with the sole intent of assessing safety, three studies (with a total of approximately 800 patch users) offered an opportunity for the participants to comment on their likes and dislikes of the product:

- In one study of 600 patch users (MR-1), only 4% noted that it caused skin to break out or caused a rash.
- In a second study of 100 patch users (MR-5), 67% noted that they liked that the patch was not irritating to skin.
- In a third study of 83 patch users (MR-6), 92.8% noted that the patch did not irritate skin.

In these three studies and three additional ones (MR-2, MR-3, and MR-4), there was no mention of skin irritation or any other safety issues in open-ended questions. One of these studies (MR-3) involved an analysis of the responses to business reply cards inserted in 15,000 Icy Hot® Patch packages; the low response rate (2.6%) and the failure to see any spontaneous comments regarding skin irritation or any other safety issues provide additional assurance that such occurrences are rarely of concern to consumers.

These data must be interpreted cautiously, as they suffer from design limitations, such as selection bias (i.e., subjects are often those who responded favorably to the "concept" of trying a pain-relief patch). Also, it must be remembered that the mechanism of action of counterirritants is based on topical stimulation of pain receptors in the skin. Consequently, mild erythema is to be expected and may be a signal of effectiveness. Thus, the failure to find any significant reports of skin irritation or other volunteered safety issues when opinions are sought is reassuring.



ICY HOT® PATCHES ARE CONVENIENT TO USE

Market research studies are well-suited to provide information on consumer likes and dislikes. Each of the six market research studies sponsored by Chattem provides direct evidence that consumers believe the Icy Hot® Patch is a convenient method of providing topical analgesia. Users in all studies were positive about the product form and application. Key benefits (e.g., ease of use, convenience, not being messy, providing pain relief directly to the affected area) were all seen as inherent in the patch technology.

When asked about product attributes, two particular "likes" related to convenience were cited in each of the six market research studies:

- Easy to use: 25.9-79.5% of patch users in each of the six studies cited this as a "like," a "true" attribute, or a "performance characteristic."
- Not messy: 13.6-95.2% of patch users in each of the six studies cited this as a "like," a "true" attribute, or a "performance characteristic."

Patch products are seen as a way to avoid the "greasy mess" associated with pain rubs.

ICY HOT® PATCHES MEET AN UNMET CONSUMER NEED

Market research studies are also well-suited to exploring consumer needs and whether the current array of products meets these needs. With respect to topical analgesia, consumer need can be assessed by determining whether consumers would abandon a currently used product for a new one, whether they would add the new product to what they currently used, and by determining what proportion of users intend to buy the new product.

The marketing studies conducted by Chattem provide data on these issues.

Consumers Believe Icy Hot® Patch is A Good Alternative to Currently Used Products

Subjects in the market research studies conducted by Chattem were generally people who had used pain rub products in the past. These subjects clearly believe that the Icy Hot® Patch is a unique product. In two studies (MR-5 and MR-6), 47% and 62.5% of respondents, respectively, reported that the Icy Hot® back patch was unique, or new and different.

A significant proportion (as high as 86% in MR-5 and 96.2% in MR-6) indicated that they would use the patch as a replacement for or in addition to their current product. The back patch was seen as particularly useful due to its larger size. Many respondents indicated that the patch was better than other products they had used (62% in MR-3). Although these market research studies were not intended to provide rigorous evidence of effectiveness, it can be noted that subjects generally found that the patch provided effective pain relief; in fact, some users noted that they experienced greater pain relief with the patch than with their current pain rub.



Consumers Intend to Purchase Icy Hot® Patch in the Future

Three studies sponsored by Chattem assessed the intent of the respondents to purchase the patch in the future. The majority of respondents (ranging from 60% in MR-1 to 84.4% in MR-6) reported that they would probably or definitely buy the patch. This high level of intent to purchase demonstrates that the Icy Hot® Patch fills a consumer need that other currently available products do not meet.

THE USE PATTERNS OF ICY HOT® PATCHES ARE UNDERSTOOD

Market research studies provide very useful information regarding who uses the Icy Hot® Patch, and where and how the patches are used. These studies indicate that consumers generally use the patches as intended: that is, they use them for the conditions specified on the product label, and do not alter the patches or use them more frequently than recommended.

Demographics of Users and Conditions Treated

A general profile of patch users can be constructed from study MR-3, in which business reply cards were placed in 15,000 Icy Hot® Patch packages. About two-thirds of the 387 respondents were female, and the average age was 60.7 years. Other studies sponsored by Chattem selected subjects who generally fit this profile: they included more women than men, with an average age older than 50. Data were not collected on race or skin type.

The Icy Hot® Patch label indicates that the product is intended for relief of minor pain associated with arthritis, simple backache, bursitis, tendonitis, muscle strains, bruises, and cramps. The available data confirm that consumers use Icy Hot® Patch for these indications. The business reply card (BRC) analysis cited above (MR-3) provides the best data on “real-world” use. The majority (73%) of BRC respondents used the patch to treat arthritis or another kind of joint pain. The most common uses were arthritis or joint pain (73%), muscle pain (42%), and backache (39%)¹. Less commonly, the patch was used to treat bursitis (10%) or other pain (10%). A study that recruited muscle/arthritis/joint pain sufferers (MR-1) indicated that approximately 55% used the patch for arthritis or joint pain, 41% for muscle soreness not from exercise, 33% for back pain, 16% for muscle soreness from exercise, 11% for tendonitis, 10% for bursitis, and 10% for all other ailments.

Two studies that recruited a total of 183 backache sufferers who used the back patch (MR-5, MR-6) indicated that the ailments treated included arthritis or joint pain (33-87%), back pain (72%), and muscle pain (21-52%).

¹ Note that respondents could report more than one ailment.



Where/How Patches Are Used

Three of Chattem's market research studies specifically analyzed where on the body the patch was used. In one study of the small patch (MR-4), 37.5% of users used the product on the knee; 13.4% on the ankle or wrist; 80.4% on the back, neck, or shoulders; 20.5% on leg or arm muscles, and 1.8% used it in another location¹. Satisfaction with use in all of these locations was high, ranging from 56.5% on the leg/arm muscles to 73.8% on the knee/elbow.

Two other studies (MR-5 and MR-6) evaluated use of the larger back patch. As would be expected, this patch was used predominantly on the back (67.5-78% on the lower back and 15.7-18% on the upper back). However, respondents in these studies also reported that they used it on the neck (3.6-13%), shoulders (9.6-23%), arms (2-3.6%), wrists (1-2.4%), hands (2%), legs (4.8-6%), knees (11-16.9%), ankles (2-4.8%), hips (6%), middle back (3.6%), feet (1.2%), side (1.2%), and other (1%).

Thus, it can be seen that the patch is most often used for the back, neck and shoulders, and is used less commonly in some other body locations, including joints.

Frequency of Use

Data on frequency of use come from several studies sponsored by Chattem. An analysis of data from 387 business reply cards (MR-3) indicated that 75% of respondents used Icy Hot® Patch once a week or more. An additional 11% used the patch at least once a month.

Detailed information on cumulative number of times patches are used was obtained from interviews with 122 of the 387 business reply card respondents (MR-4). These respondents reported that the median² number of times the patch was used by indication was: 6.0 for arthritis/joint pain; 4.0 for back pain; 4.5 for muscle soreness not from sports; 3.0 for muscle soreness from sports.

Two additional market research studies conducted by Chattem provide only limited data, in that subjects were only given one box of the product (containing 3-5 patches) to evaluate. In one study of the small patch (MR-1), subjects used an average of about 4 1/2 patches in a 2-week period. In a second study of the back patch (MR-5), subjects used the back patch an average of 2.6 times in the 1-week usage period. Approximately half used the back patch 1-2 times per week, and only 12% used it 4 or more times per week.

Subsequent questioning in these studies focused more on *anticipated* frequency of use than on actual use. In MR-1, 1,116 respondents were read a description of the Icy Hot® Patch concept and asked how often they anticipated that they would use the patch; 24% said once a day or more; 31% said several times a week, and 15% said once a week. The average number of uses anticipated per month was 14.6. In study MR-5, 100 patch users were asked to anticipate how frequently they would use the patch in the future; 7% said once a day or more; 33% said several times a week; and 15% said once a week. The average use anticipated was 1 to 2 times a month.

² The median provides the best estimate, as outliers distort the mean.



Duration of Use

One study (MR-5) questioned 100 users of the back patch about the length of time they wore the patch. In this study, most (68) users reported that they wore the patch for 4 hours or more. A majority of respondents reported that they wore the patch in the evening or while they slept.

Number Used/Modifications of the Patch

Most users use only one or two patches at a time. In study MR-4, which involved the smaller patch, 58.9% of 122 patch users reported that they used only one patch at a time. The median number of patches used by indication was: 1 for arthritis/joint pain; 1 for back pain; 1 for muscle soreness not from sports; and 2 for muscle soreness from sports.

There is little evidence that consumers use the Icy Hot® Patch in ways that were not intended. Two studies (MR-5 and MR-6) reported that 86% of users did not alter the Back Patch in any way. Of those who did, two-thirds cut it in half.



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-1. Pain Patch Concept Evaluation and In-Home Use Test	Study done to assess concept of pain patch, evaluate 2 formulations, and identify sales opportunities.	<p>Concept of a pain patch was assessed by 1,116 men and women who were muscle/arthritis/joint pain sufferers. 72% were women; 47% were 55 or older.</p> <p>947 who were "positive" about the concept were sent 5 back patches.</p> <p>600 of the 947 used the patch at home and 600 completed telephone interview.</p>	Of 600 users, 4% mentioned "caused skin to break out/rash" as a dislike.	<p>Users were positive about the product form and application.</p> <p>Likes included:</p> <p>Easy to apply (35%)</p> <p>Not messy (18%)</p>	<p>89% experienced adequate or very adequate pain relief.</p> <p>60% of subjects indicated that they probably or definitely would buy the patch.</p> <p>39% would totally replace their pain rub with the patch.</p> <p>90% of users who were part of both the concept and the use studies would use the patch alone (as a replacement) or in addition to their current rub.</p>	<p>Subjects in the use study reported using an average of about 4.5 patches in a 2-week period. (Note: subjects were sent only 5 back patches)</p> <p>Ailments treated included: arthritis or joint pain or discomfort (~55%); backache (~33%); muscle soreness from exercise (~41%); muscle soreness not from exercise (~16%); tendonitis (11%), bursitis (10%) and others (~10%). (Note: Could report more than one ailment.)</p>



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH (continued)

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-2. Icy Hot® Patch Focus Group: Test Product and Advertising Qualitative Research	<p>Focus groups evaluated 5 different ads for Icy Hot® Patch.</p> <p>Results were qualitative in nature, rather than quantitative.</p>	<p>Subjects were men and women who were muscle/arthritis/joint pain sufferers (age 35-70). There were 4 groups with an unknown number of participants in each group.</p> <p>All were described as having used the product. However, the circumstances of use were not described.</p>	<p>There were no spontaneous comments regarding safety issues.</p>	<p>Focus groups supported consumer interest in the patch. Key benefits (ease of use, convenience, not messy, providing pain relief directly to the affected area) were seen as being inherent in the patch technology. The patch was a method for avoiding the "greasy mess" associated with pain rubs.</p>	<p>Subjects reported greater pain relief (particularly longer lasting relief) with the patch than their current pain rub.</p>	<p>No details provided on product use.</p>



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH (continued)

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-3. Business Reply Cards (BRCs): Open-Ended Responses	Individuals who purchased Icy Hot® Patch could complete and send in an attached business reply card.	Of 15,000 BRCs inserted in February 01; 387 responses were received (response rate of 2.6%).	There were no spontaneous comments regarding safety issues.	Users were positive about the product form and application. Attributes indicated by subjects as "true" about the product: Not messy (86%) Easy to use (79%) Stays on well (70%)	61% found the patch to be effective. 80% indicated they would likely repurchase the product. Of 261 respondents who had used other products, 62% indicated the patch was better than other products. 71% rated the product as excellent or very good.	Average age of respondents was 60.7 years; about 2/3 were female. Ailments treated included arthritis or joint pain (73%); muscle pain (42%); backache (39%); bursitis (10%); and others. 64% of respondents had purchased patch only 1 time. 75% used patch once a week or more. 86% of arthritis sufferers claim weekly usage.
	Data compiled from open-ended questions posed in BRCs (above) about likes and dislikes of Icy Hot® Patch.	339 "likes" were mentioned; 199 "dislikes" were mentioned.	There were no spontaneous comments regarding safety issues.	Users were positive about the product form and application. Likes included: Ease of use (31.0%) Not messy (13.6%) Convenience (7.7%)	31.0% liked the effectiveness of the product.	Little information on product use. 1.0% disliked that there were no directions for how long to use.



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH (continued)

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-4. Business Reply Card Follow-Up: Inquiries to Respondents	Phone interviews conducted with individuals who returned BRCs (above).	Phone numbers were available for 330 respondents of the 387 in MR-3; interviews were completed with 122.	There were no spontaneous comments regarding safety issues.	Users were positive about the product form and application. Likes included: Stays on (27.7%) Easy to use (25.9%) Not messy (23.2%)	80.3% experienced adequate or very adequate pain relief. 71.5% would probably or definitely repurchase the patch. 62.5% liked the patch more than their usual product.	77.7% had purchased patch more than once. Median number of times patch was used by indication: arthritis/joint pain (6.0); back pain (4.0); muscle soreness not from sports (4.5); muscle soreness from sports (3.0). 58.9% did not use more than 1 patch at a time. Median number of patches used by indication was usually 1.0. Ailments treated included arthritis or joint pain (73.2%); back pain (51.8%); muscle soreness (50%); and others. 37.5% used on knee; 13.4% on ankle or wrist; 80.4% on back, neck, or shoulders; 20.5% on leg or arm muscles, 1.8% other.



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH (continued)

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-5. Icy Hot® Back Pain Patch Concept and Use Test	Study done to determine if introduction of a large size patch will cannibalize from the existing market for small patches.	150 backache sufferers were sent a sample of 3-5 Back Patches. 100 who had used the patch completed a phone interview 1 week later.	<p>Top 2 Box %: Not irritating the skin (67%)</p> <p>A primary dislike among rejectors (not defined) was skin irritation (21%). Number of rejectors not reported.</p>	<p>Convenience was one of the top 2 reasons cited for why respondents liked the patch.</p> <p>Primary likes (Top 2 box %) were:</p> <p>Easy to apply (73%) Not messy (78%)</p>	<p>47% felt product was unique (Top 2 Box %)</p> <p>23% of subjects would completely replace their old product with Icy Hot® Back Patch</p> <p>63% would use the larger patch in addition to their current pain relief method</p>	<p>86% did not alter the Back Patch to meet another pain relief need.</p> <p>Mean frequency of use was 2.6 times/week (subjects only sent 3-5 patches to use in 1-week period). 51% used 1-2 times/week; 12% used 4+ times/week.</p> <p>Average length of time worn was 4.09 hours.</p> <p>Ailments treated included arthritis or joint pain (33%); back pain (72%); muscle soreness (52%); and others.</p> <p>Patch was used predominantly on back (78% lower back; 18% upper back). Also used on neck (13%), shoulders (23%), arms (2%), wrists (1%), hands (2%), legs (6%), knees (11%), ankles (2%), and other (1%).</p>



SUMMARY OF MARKET RESEARCH STUDIES ON ICY HOT® PATCH AND ICY HOT® BACK PATCH (continued)

Study	Purpose	Subjects	Safety	Convenience	Meets Consumer Need	Product Use
MR-6. Home Use Test of Icy Hot® Back Patch Among Users of Small Patch who Returned BRC	Individuals who used small pain patch and returned BRC were contacted to evaluate idea of large back patch.	Back patch samples (number not specified) sent to 95 individuals; 83 used product and were interviewed.	92.8% were in the Top 2 Box % with respect to "does not irritate skin"	Performance characteristics (Top 2 Box %) included: Easy to apply (79.5%) Not messy (95.2%)	62.5% felt the product was new and different (Top 2 Box %). 78.3% prefer it to the original (smaller patch). 84.4% indicate they would probably or definitely purchase the product (Top 2 Box %). 60.2% report it would completely replace their old product. 36.1% report they would use the patch in addition to their old product.	Ailments treated included arthritis or joint pain (87%); back pain (72%); muscle soreness (21%); and others. 85.5% did not modify the Back Patch in any way. Of those who did, 2/3 cut it in half. Patch was used on lower back (67.5%), knees (16.9%), upper back (15.7%), shoulders (9.6%), hips (6%), legs (4.8%), ankles (4.8%), neck (3.6%), arms (3.6%), middle back (3.6%), wrists (2.4%), feet (1.2%), and side (1.2%).

